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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,380	02/24/2004	Mary Jane Cardosa	2316.2009-000	3579

22852 7590 03/01/2007

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/786,380	CARDOSA ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 35-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 35-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *page 5 of IDS 11/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application has been transferred to examiner Chen of Art Unit 1648. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to accordingly.

2. Applicant's response and amendment filed December 14, 2006 is acknowledged and entered. Claims 1 and 35-46 are pending and under examination. In view of the new grounds of rejection, particularly the obviousness type double patenting rejection, this Office action is made non-final.

Response to Amendment/Arguments

3. The rejection of claims 18, 19, 33 and 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is moot in view of the cancellation of these claims.

4. The rejection of claims 15, 17-20, 33 and 34 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is moot in view of the cancellation of these claims.

5. The rejection of claims 1 and 11-34 under 35 U.S.C. 102(b) as anticipated by Cardosa *et al.* (WO 98/13500) is withdrawn in view of Applicant's persuasive arguments. The instant application is a continuation of USSN 09/147,919, which is a 371 of PCT/EP97/05214, filed September 23, 1997. The earliest effective U.S. filing date for this application is September 23, 1997. Therefore, the art rejection is withdrawn.

Specification

6. (*New Objection*) The specification is objected to because it needs to be updated to reflect the status of USSN 09/147,919, now U.S. Patent 6,869,793.

Claims Summary and Interpretation

7. The claims are drawn to a recombinant modified vaccinia virus Ankara (MVA) comprising a DNA sequence encoding a dengue virus antigenic epitope of serotype 1, 2, 3 or 4. Given that an epitope is, by definition, antigenic, the term "antigenic epitope" is interpreted as "epitope". Further, the Office understands that the DNA sequence encodes an antigen comprising an epitope, since epitopes can be conformational (structure is dependent on surrounding amino acids that are not part of the epitope itself).

In another embodiment, the DNA sequence encodes a preM antigen, E antigen, or NS1 antigen of dengue virus, wherein each antigen comprises an epitope.

Specifically, the DNA sequence is inserted into the MVA at the site of a naturally occurring deletion, such as deletion site II. The DNA sequence is under transcriptional control of the vaccinia virus early/late promoter P7.5.

Also claimed is a composition comprising the recombinant MVA and a pharmaceutically acceptable carrier or diluent. The composition is used to generate an immune response in an animal, such as a human, upon administration. Also claimed is a cell, a eukaryotic cell, comprising the recombinant MVA. The cell is used to produce recombinant MVA when cultured under suitable conditions and subsequently isolated.

Claim Objections

8. (*New Objection*) Claim 1 and dependent claims 35-46 recite improper grammar (emphasis added): "A recombinant MVA containing and capable of expressing one or more DNA sequence encoding a dengue virus antigenic epitope." Correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(*New Rejection*) Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 37 recites an improper Markush group. Appropriate language is (emphasis added), "selected from the group consisting of a DNA sequence encoding a PreM antigen, a DNA sequence encoding an E antigen, and a DNA sequence encoding an NS1 antigen."

Further, claim 1, from which claim 37 depends, refers to antigenic epitopes, not "antigens" as claimed in claim 37. Consistent language is required.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not

identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(*New Rejection*) Claims 1 and 35-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent 6,869,793. Although the conflicting claims are not identical, they are not patentably distinct from each other. The patented claims are drawn to a composition comprising a recombinant MVA expressing a dengue virus antigen from serotype 1, 2, 3 or 4. The difference between the two claim sets is that the patented claims specifically recite the structural component of a vector/plasmid that contains the DNA sequence encoding the

dengue antigen. However, it would have been obvious to use a vector/plasmid in the recombinant MVA construct because claim 40 of the instant application is drawn to a recombinant MVA wherein the DNA sequence encoding the dengue antigen is under transcriptional control of the vaccinia virus early/late promoter P7.5, which is for use in a plasmid construct. Therefore, the instant claims are rejected as obvious over the patented claims.

Conclusion

11. No claim is allowed. A copy of the page 5 of the IDS filed 11/7/05 is attached to this Office action. A date has been assigned to references C28, C29 and C30.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 2/27/07

STACY B. CHEN
PRIMARY EXAMINER